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ASAM Issues Public Policy Statement on the Regulation of the Treatment of Opioid Use Disorder with Methadone

Nation's leading association of addiction specialist physicians and other clinicians recommends ways to improve access to, and the quality of, methadone treatment for opioid use disorder

Rockville, MD – Despite a long history and robust scientific evidence supporting the effectiveness of methadone for the treatment of opioid use disorder (OUD), regulatory barriers and stigma hinder patient access to this life-saving treatment. In response, the American Society of Addiction Medicine (ASAM) today issued a <u>Public Policy Statement on the Regulation of the Treatment of Opioid Use Disorder with Methadone</u>, which highlights specific policy recommendations to improve both access to, and the quality of, methadone treatment for OUD by making it more patient-centered and integrated with other medical care.

"Deaths from opioid-involved poisonings have sadly skyrocketed in recent years, underscoring the critical need to expand access to Food and Drug Administration (FDA)-approved medications for the treatment of opioid use disorder, including methadone," said William F. Haning, III, MD, DLFAPA, DFASAM, president of the American Society of Addiction Medicine. "Recognizing the barriers that existing laws and regulations have posed for decades, it is past time to revisit federal and state policies with an eye towards making treatment of OUD with methadone more patient-centered and integrated with other medical care."

Overly stringent, non-evidence based policies are significant contributors to underutilization of this therapeutic modality for OUD. In 2020, a mere 2 percent of specialty addiction residential treatment settings offered methadone. Most counties in the United States do not have a single opioid treatment program (OTP), a major obstacle to evidence-based addiction treatment at a time when <u>drug overdose deaths are at an all-time high</u>.

Since methadone was determined by the FDA to be safe and effective for treating OUD in the early 1970s, the medication has faced a climate of skepticism and hostility driven by stigma and erroneous beliefs. As a result, the federal government has strictly regulated the provision of methadone for OUD treatment. These regulations specify criteria on eligibility, initial

methadone dosages, supervised dosing, and largely restrict the delivery of methadone treatment to a closed system of regulated clinics. Compounding access problems, some states and localities add requirements that are not evidence-based and are even more restrictive than federal regulations. Some researchers have noted that the highly regulated system of methadone-specific clinics in the United States may also reflect racism and contribute to health disparities among different people with OUD.

To enhance the quality of and increase access to methadone for the treatment OUD, ASAM has put forth more than 20 specific policy recommendations regarding the regulation of the treatment of OUD with methadone, including as follows:

- Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) regulations should allow the initial medical evaluation for treatment of OUD with methadone by audio-video telemedicine when deemed by the OTP medical director as necessary and appropriate.
- SAMHSA should revise regulations regarding patient admission criteria for inclusion of current OUD of any duration or a history of OUD, warranting medication treatment for OUD.
- SAMHSA should specify time in treatment requirements for unsupervised dosing in practice guidelines rather than in federal regulations.
- SAMHSA should make permanent the methadone unsupervised dosing and OTP-related telehealth flexibilities implemented during the COVID-19 Public Health Emergency with continued study of the impact of these flexibilities.
- SAMHSA and DEA regulations should allow pharmacy dispensing and/or administration of methadone that has been prescribed for patients who meet certain criteria by a legally authorized prescriber of controlled medications who is affiliated with an OTP, is an addiction specialist physician, or is a physician who has met specific qualifications.
- States should align their OTP regulations with federal regulations and current medical best practices to promote access to and retention in treatment.
- SAMHSA should ensure that OTP accreditation standards are simplified by establishing them directly, or by re-evaluating standards established by accrediting bodies.

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About the American Society of Addiction Medicine

The American Society of Addiction Medicine (ASAM), founded in 1954, is a professional medical society representing over 6,600 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention and promoting the appropriate role of physicians in the care of patients with addiction. For more information, visit www.ASAM.org.